



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 24 2004

Re: Xigris
Docket Nos. 02E-0099, 02E-0184, and 03E-0255

The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

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OFFICE OF PETITION

now Re-37806

Dear Acting Director Dudas:

This is in regard to the patent term extension applications for U.S. Patent Nos. 4,775,624; 5,681,932; and 5,270,040 filed by Eli Lilly & Company under 35 U.S.C. § 156. The patents claims Xigris (drotrecogin alfa), BLA 125029/0.

In the November 25, 2003, issue of the Federal Register (68 Fed. Reg. 66112), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before May 24, 2004, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Brian P. Barrett
Eli Lilly & Company
Patent Division, BPB
Lilly Corporate Center
Indianapolis, IN 46285

LILLY PATENT DIVISION Fax:317-276-5172

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CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office at 703-872-9306 on the date shown below.

D'LEAH R. SANDERS

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Signature

D'Leah R. Sanders

8/31/04
Date

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent No. RE 37,806.

Patentee : Brian W. Grinnell
Assignee : Eli Lilly and Company
Issue Date : June 23, 2002
Docket No. : X6606M

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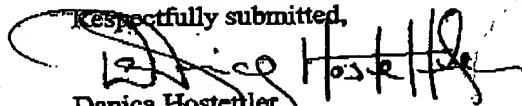
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TECH CENTER 1600/200

Sir:

Applicant in this application filed a "Request for Extension of Patent Term Under 35 U.S.C. 156" on January 11, 2002. Applicant has received no further communication from the Patent and Trademark Office, or the Food and Drug Administration, regarding this application. It would be appreciated if the Office would advise Applicant of the current status of this application.

Respectfully submitted,


Danica Hostettler
Attorney for Applicant
Registration No. 51,820
Phone: 317-276-3711

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288
August 31, 2004